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The FDA, Preemption, and Public Safety: Antiregulatory Effects and Maddening Inconsistency

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Most people think of preemption as a technical, constitutional doctrine, but it is pivotally important to health and safety and opens the door to broad judicial discretion. The Rehnquist and Roberts Courts' jurisprudence, with its support for both business and preemption, has been distinctly antiregulatory, invalidating major state public health rules in occupational safety, tobacco control, and motor vehicle safety, among other things.[1] And apart from these antiregulatory stances, the Supreme Court has also been maddeningly inconsistent. Consider three relatively recent cases.

In its 2008 decision in *Riegel v. Medtronic, Inc.*, the Court held that federal law bars injured consumers from challenging the safety or effectiveness of medical devices approved by the Food and Drug Administration.[2] A year later, however, in *Wyeth v. Levine*, the Court came to the opposite conclusion, ruling that injured consumers could sue pharmaceutical companies for failing to warn about the risks of taking brand-name drugs.[3] Yet on June 23, 2011, in *PLIVA, Inc., v. Mensing*, the Court found that injured consumers could not bring failure-to-warn claims for injuries caused by FDA-approved generic pharmaceuticals.[4] Thus, in less than four years, the Court barred state health and safety litigation for FDA-approved medical devices, allowed failure-to-warn claims for branded pharmaceuticals, and then barred those same claims for generic pharmaceuticals.[5]

What is the rational basis for treating brand-name and generic medicines differently when, by law, the products must be equivalent? Or for treating brand-name drugs and medical devices differently even though they go through similar approval processes? As Justice Sotomayor (dissenting in *PLIVA*) put it, this "leads to so many absurd consequences that I cannot fathom that Congress would have intended to preempt state law," while even Justice Thomas, writing for the Court, admitted this outcome "makes little sense."

In order to figure out how we reached this predicament, let's take a step back and find out more about the perversion of the preemption doctrine, the newest ruling on generic medicines, and the public health value of consumer litigation.

Public Health and Preemption

Preemption is a doctrine undergirded by the supremacy clause, which holds that federal law prevails over state law if there is a conflict. The two cornerstones of preemption are Congress's intent as the "ultimate touchstone" and the strong presumption against preemption when the state exercises its historic police powers.

The Supreme Court has repeatedly perverted these two key criteria. Congress intended for federal and state food and drug regulation to work side by side, each providing a significant yet distinct layer of consumer protection. If Congress thought state lawsuits posed an obstacle to its objectives, it surely would have said so explicitly at some point during the Food, Drug, and Cosmetic Act's seventy-year history. How could Congress have intended such irrational inconsistencies between brand-name and generic drugs?

Is it reasonable for the nation's highest court to conclude that Congress actually intended to bar injured patients from judicial recourse against companies that, knowing the risks, aggressively market hazardous drugs or medical devices? The public might express even greater skepticism if tort immunity were granted to corporations that defraud the agency. But that is precisely the position of the Supreme Court, which permits a corporation to use FDA approval as a shield against litigation even if it deceived the agency into granting that approval. In *Buckman Company v. Plaintiffs' Legal Committee*, the Court held that state law fraud-on-the-FDA claims were preempted.[6] The Court split four against four when asked if consumer litigation was also preempted when drug companies defraud the agency.[7] Since Chief Justice Roberts did not participate in the decision, the Court would likely side with the pharmaceutical industry, even if it intentionally hides safety data.

Consumer safety regulation, moreover, is a classic state police power. State public health regulation has a long history and remains a robust activity today. The common law has traditionally granted causes of action for consumer products that are defective or for which companies fail to adequately disclose known risks. And although the Court admonishes against preemption of state safety rules, it did not even mention this doctrine in *Riegel*, *PLIVA*, or *Buckman*.

The Irrational Consequences of *PLIVA*

In the aftermath of *PLIVA*, an injured consumer's access to the civil justice

system turns solely on "the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic."[8] Yet 78 percent of all prescription drugs dispensed are generics, and with patents expiring this year on blockbuster drugs like Lipitor, Plavix, and Zyprexa, the generic market share will rise further.[9] This is happening by design—the express purpose of the Hatch-Waxman Amendments is to make generic drugs affordable and available. State law, moreover, authorizes pharmacists to substitute generic for brand-name drugs when filling prescriptions. Currently, the prescriptions for more than 90 percent of drugs for which a generic version exists are filled with generics. Consequently, most consumers harmed by medications now lack access to justice.

Generic manufacturers—often large, multinational companies—now have little incentive to monitor and disclose safety risks. Brand-name manufacturers also may leave the market once the generic version is available, so no one will have the incentive to strengthen warning labels or to remove dangerous products from the market.

The Value of Consumer Safety Litigation

Why do we need litigation when the FDA already has a duty to protect the public's safety? Lawsuits bring advantages for the agency as well as for consumers because gaping resource and informational deficits hamper its oversight. The FDA's responsibilities are vast and cover 25 percent of all consumer spending, including food, drugs, vaccines, and medical devices. Yet it lacks adequate staffing and resources, even as its mandate and public safety concerns continue to increase, and it does not have the information it needs for effective oversight. Consequently, it is forced to rely on manufacturers to find and disclose hazards.

Further hampering the FDA's oversight is the fact that its approval decisions consider relatively small numbers in clinical trials, so that any given drug's full safety and effectiveness profile emerges only after it is marketed to a large population. Tort litigants, unlike the FDA, have subpoena power, and discovery can be a potent way to inform the agency and public of undisclosed risks. Litigation can also be socially and politically mobilizing: uncovering poor industry practices can drive regulatory reform.

These resource and informational deficits have resulted in high-profile regulatory failures involving the FDA-approved COX-2 selective nonsteroidal anti-inflammatory drugs Vioxx and Celebrex, the type 2 diabetes drug Avandia, and the Dalkon Shield intrauterine device. In 2009, the FDA issued a "black box warning" about the very drug at issue in *PLIVA*—metoclopramide, also known as Reglan. Litigation revealed that manufacturers knew the risks but did not promptly inform the FDA. State tort law provides a system of civil justice designed to compensate patients, deter unreasonably hazardous conduct, and encourage innovation in product design, packaging, labeling, and advertising. Tort law, therefore, closes regulatory gaps in the FDA's premarket approval process, providing much-needed postmarketing surveillance.

In the end, the public is caught in a catch-22. While the FDA is perceived as ineffectual and the hazards of widely-used drugs and devices continue to be revealed, the Supreme Court makes it harder for patients to discover wrongdoing—even fraud—and to be fairly compensated for their avoidable injuries.

1. L.O. Gostin, "The Deregulatory State," *Hastings Center Report* 38, no. 2 (2008): 10-11.
2. *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).
3. *Wyeth v. Levine*, 555 U.S. 555 (2009).
4. *PLIVA, Inc., v. Mensing*, No. 09-993, Slip Opinion (2011).
5. L.O. Gostin, "Regulating the Safety of Pharmaceuticals: The FDA, Preemption, and the Public's Health," *Journal of the American Medical Association* 301 (2009): 2036-37.
6. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).
7. *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008).
8. *PLIVA, Inc., v. Mensing*, No. 09-993, Slip Opinion (2011), at 19 (Sotomayor, J., dissenting).
9. IMS Institute for Health Care Informatics, "The Use of Medicine in the United States: Review of 2010," April 2011, http://www.imshealth.com/deployedfiles/imshealth/Global/Content/IMS%20Institute/Static%20File/IHII_UseOfMed_report.pdf.